

REMARKS

Independent claims 1 and 5 have been amended, without prejudice, to recite a specific list of phytoestrogens and a specific list of retinoid boosters. Basis for this amendment may be found on page 34, lines 5-12 and the Tables on pages 25, 30-31 of the specification.

The Present Invention

The present invention addresses the problem of providing an alternative treatment for the signs of aging by employing a unique combination of retinoid, retinoid booster, and phytoestrogen. However, it has been discovered that phytoestrogens, while boosting the benefits of retinoids, destabilize the retinoid by inducing oxidation of retinol. The present invention addresses the problem of providing a stable product by preventing any undesired interaction of the retinoid and the boosting agents and the phytoestrogens during storage.

35 USC § 112

35 U.S.C. 112, first paragraph

The Specification and Claims, as amended, Provide Enablement for
"Retinoid Boosters" and "Phytoestrogens"

The specification was objected to and Claims 1-2 and 5-6 were rejected under 35 U.S.C. 112, first paragraph. Applicants traverse this rejection and respectfully submit that the Specification is enabling for all the phytoestrogens, as claimed. To clarify, Claim 1 has been amended, without prejudice, to recite the specific list of

phytoestrogens found at page 6 of the Specification. Further, claims 1 and 5 have been amended, without prejudice, to recite a specific list of retinoid boosters. Applicants respectfully submit that these amendments render the objections moot.

35 U.S.C. 112, second paragraph

Claims 1-2 and 5-6 are rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants traverse this rejection but respectfully submit that the claim amendments render this rejection moot, as discussed above with reference to the first paragraph of 35 USC § 112.

35 USC § 103

Claims 1-2 and 5-6 were rejected under 35 USC § 103 as being unpatentable over Cohen et al., Weidenboerner et al., Mishra et al., and Jones et al., in view of Soares et al.

According to the Office Action, Cohen et al., Weidenboerner et al., Mishra et al., and Jones et al. teach the claimed compounds retinoic acid, isoflavones (phytoestrogens), farnesol, and clotrimazole, respectively, as useful for treating fungal infections.; Claims 1-2 and 5-6, and the primary references, differ as to :

- 1) the concomitant employment of these medicaments.
- 2) administration levels of the medicaments, and
- 3) administration of the medicaments in separate containers.

Applicants respectfully traverse this rejection. Regarding difference (1), firstly, there is not suggestion or motivation to combine the references and, secondly, Applicants have shown unexpected results in the combination of ingredients, i.e. synergistic results from combination of retinoid and phytoestrogen. Regarding difference (2), Applicants have claimed cosmetically effective amounts. Regarding difference (3), the particular means by which the compositions are separated is new and inventive, and critically contributes to the stability of retinoids without compromising overall efficacy.

Additionally, Applicants respectfully submit that the rejection has been rendered moot by the claim amendments. The claims, as amended, recite a specific list of different boosters and a specific list of different phytoestrogens than those disclosed in the cited references.

"1) the concomitant employment of these medicaments"

There is no suggestion or motivation to combine the references. Each of the four cited references addresses a different compound, each having anti-fungal activity toward different fungi. In fact, the references teach away from the combination, as it is evident from the references alone or in combination that different agents have anti-fungal activities toward different fungi, and there is no reason provided to believe that a material having anti-fungal activity toward one particular fungus will also have anti-fungal activity toward a different fungus. For example, Jones et al. indicate that clotrimazole, while being effective against *Aspergillus*, needs to be combined with an antibiotic in order to be effective against *Candida* infections. Accordingly, there is no suggestion that all anti-fungal agents have activity against all fungi and, therefore, no

suggestion or motivation for combining anti-fungal agents and/or the references that disclose them.

Moreover, Applicants have demonstrated strong *synergies* in the combination of retinoids with phytoestrogens. See Specification, Tables 4 and 5 at pp. 48-49. At the same time, Applicants have demonstrated that phytoestrogens contribute to loss of stability of retinoids and therefore require a dual compartment package. See Specification, Example 5, Tables 6 and 7. These are *clear and convincing*, unexpected results, rebutting any *prima facie* case of obviousness if it had been made out .

Additionally, the combination of the cited documents fails to disclose the particular boosters and phytoestrogens claimed, either alone or in combination with retinoids.

"3) administration of the medicaments in separate containers"

None of the cited documents addresses the problem of retinoid stability in the presence of phytoestrogens and/or boosters. Consequently, there is no suggestion for a person skilled in the art to try to physically separate the retinoids, the boosters, and the phytoestrogens. For example, Table 1 at page 40 of the Specification shows that glycerhetinic acid contributes to 1.6-fold and linoleic acid contributes to 3.4-fold increase in the rate of retinol loss. Absent the hindsight of Applicants' specification, there would be no suggestion or motivation for one skilled in the art to separate the retinoid and booster compositions.

In particular, none of the cited references teaches or suggests a two-part composition which contains in one part a retinoid, and in the second part a retinoid booster and a phytoestrogen. As discussed above, Cohen et al., Weidenboerner et al., Mishra et al., and Jones et al. do not teach or suggest the combination of components claimed presently, i.e., retinoid + booster + phytoestrogen. There is no teaching or suggestion of how to put these components together to achieve a stable skin care product. Soares et al. do not remedy the defect because they fail to teach or suggest which combinations of components are placed together and which are kept separate. Only with the hindsight of the present invention is this combination possible.

Soares et al. (USPN 5,914,116) disclose two separate containers for separating two different skin actives **for two different benefits**, with one container containing a first active providing a first benefit and the second containing a second active providing a second and different benefit. However, Soares et al. fail to disclose the need to separate phytoestrogens from retinoids. In contrast, the present invention is directed to two separate compositions with one intended to boost the benefit of the other. According to the present invention, the two compositions are intended to be applied simultaneously or consecutively, but are kept separately for stability reasons. Independent claim 5, as worded to relate to "first benefit", is intended to clearly convey that the specified retinoids and the phytoestrogens, although separated into two compartments, are there for the same benefit (as compared with the cited art). The first composition provides a first benefit to the skin while the second composition works to boost or enhance the effect of the first benefit.

As such, Soares et al. fail to provide a suggestion or motivation for the particular way the compositions of the present invention are stored separately.

CONCLUSION

Reconsideration of the rejection is respectfully requested in view of the above claim amendments and remarks.

It is respectfully requested that the application be allowed to issue.

If a telephone conversation would be of assistance, Applicant's undersigned attorney invites the Examiner to telephone at the number provided.

Respectfully submitted,



Ellen Plotkin
Registration No. 36,636
Attorney for Applicant(s)

(201) 840-2253